

## II. Research Involving Vertebrate Animals

### A. Introduction

ATP will fund research involving live vertebrate animals. Research involving live vertebrate animals must be in compliance with all applicable federal statutes, federal regulations, and policies.

For research involving live vertebrate animal subjects, NIST has procedures that require NIST as an institution to approve documentation in addition to ATP review and approval.

NIST and ATP follow the regulations in the Animal Welfare Act at 7 U.S.C. §§ 2131–2159. In addition, the Institutional Animal Care and Use Committee (IACUC) should follow the recommendations in the National Research Council's *Guide for the Care and Use of Laboratory Animals* (the *Guide*) as a basis for developing and implementing an institutional animal care and use program.

These policies do not affect applicable state or local laws or regulations that may impose more stringent standards for the care and use of laboratory animals.

The requirements described below do not apply to proposed research using preexisting images of animals (e.g., a wildlife documentary or pictures of animals in newscasts) or to research plans that *do not* include animals that are being cared for, euthanized, or used by the project participants to accomplish research goals, teaching, or testing.

These requirements also do not apply to obtaining animal materials from commercial processors of animal products or to animal cell lines or tissues from tissue banks.

### B. IACUC Review and Compliance

NIST and ATP require that the IACUC that reviews and approves the care and use of live vertebrate animals maintain and comply with appropriate institutional assurances, certifications, or accreditations.

Depending on the research and type of live vertebrate animal involved in the research, NIST and ATP require that the IACUC maintain at least one of the following:

1. documentation of an Animal Welfare Assurance from the Office of Laboratory Animal Welfare (OLAW) of the Public Health Service/National Institutes of Health (PHS/NIH); or
2. documentation of a United States Department of Agriculture (USDA) Animal Welfare Act certification; or

3. if only using rodents, birds, or fish, and the above USDA or OLAW documents have not been attained, evidence of full accreditation from the Association for the Assessment and Accreditation of Laboratory Animal Care (AAALAC).

### C. Animal Study Protocols

NIST and ATP require that each use of live vertebrate animals be reviewed and approved through the use of an Animal Study Protocol (ASP). The ASP must be completed by the Principal Investigator or designee and reviewed and approved by the IACUC where the animals will be housed, cared for, and manipulated before any research has started.

NIST and ATP recommend that an approved ASP should include the elements suggested by OLAW. These elements can be found online at <http://grants.nih.gov/grants/olaw/olaw.htm>.

Please note: An example of an ASP or an ASP that is similar to what may eventually be submitted to an IACUC for review is not acceptable.

Also, if the ASP includes tasks not applicable to the ATP project, or if the ASP is supported by multiple funding sources, you must include a brief description of what portions of the ASP are specifically included in the ATP project. In addition, a nonduplication-of-funding letter indicating that no other federal funds will be used to support the tasks ATP will pay for must be submitted before issuance of an award.

### D. Required Documentation

You are required to indicate on Form NIST-1262 or Form NIST-1263, at item 13.E (see the *ATP Proposal Preparation Kit*), whether your research will involve the use of live vertebrate animals. The documentation requirements for the use of live vertebrate animals are listed below. In addition, a timeline for the submission of required documents is presented in Appendix 6.

#### 1. Live Vertebrate Animal Research Beginning in Year 1

If your research proposal includes plans to use live vertebrate animals in the first year, the following is required at Gate 3:

- a. a signed copy of the IACUC approved ASP;
- b. documentation of the IACUC approval indicating the approval and expiration dates of the ASP; and
- c. if applicable, a nonduplication-of-funding letter.

#### 2. Live Vertebrate Animal Research Beginning After Year 1

If your research proposal includes the use of live vertebrate animals beginning after year 1, the following documentation is required at Gate 3:

- a. the name of the organization(s) that may be performing the animal studies;

- b. an indication of whether the organizational IACUC has an appropriate OLAW Assurance, USDA certification, or AAALAC accreditation; and
- c. a timeline for the use of live vertebrate animals, including an approximate date of IACUC approval.

Before live vertebrate animal studies may begin, the required documents mentioned in Section D.1 of this chapter must be reviewed and approved by ATP and NIST.

### 3. Continuing Review of Animal Study Protocols

ATP requires documentation of annual continuing approval of all ASPs. The awardee is required to submit, as it occurs, documentation from the cognizant IACUC that continuing approval has been granted. In addition, ATP requires that all forms and/or amendments submitted to the IACUC for continuing approval also be submitted to ATP.

## E. Contact Information

If you have any questions regarding the use of animal subjects in research, please call the ATP Human and Animal Subjects Advisor at 301-975-8779.

The information contained in this booklet is also available on the ATP website at <http://www.atp.nist.gov/atp/helpful.htm>.

## F. Definitions

The following definitions can be found in the Animal Welfare Act at 7 U.S.C. §§ 2131–2159 or in the National Research Council's *Guide for the Care and Use of Laboratory Animals*.

**Animal Study Protocol:** A document that is submitted to an IACUC that outlines the care and use of animal subjects in a research setting. The *Guide* at page 10.

**IACUC:** The Institutional Animal Care and Use Committee. The IACUC is appointed by the responsible administrative official at each institution and is charged with overseeing and evaluating the institution's animal program, procedures, and facilities to ensure they are consistent with all applicable statutes, regulations, and policies. The *Guide* at page 9.

**Vertebrate Animal:** Any live dog, cat, nonhuman primate, guinea pig, hamster, rabbit, or any other warm-blooded animal that is being used or is intended for use in research, teaching, testing, experimentation, or exhibition purposes.

In addition, ATP considers live vertebrate animals to include rats of the genus *Rattus*, mice of the genus *Mus*, birds, and any farm animal or other warm-blooded animal.